

DP Barcode: D240854

MRID No.: 443874-06

DATA EVALUATION RECORD
§ 71-1(A) - AVIAN SINGLE-DOSE LD₅₀ TEST

1. **CHEMICAL:** Cloquintocet-mexyl **PC Code No.:** 999999

2. **TEST MATERIAL:** CGA-185072 **Purity:** 91.6%

3. **CITATION**

Authors: B.Hakin, A.J.Johnson, A.Anderson, and I.S.Dawe

Title: Acute Oral Toxicity of CGA-185072 to the Bobwhite Quail

Study Completion Date: December 1, 1988

Laboratory: Huntington Research Centre, Ltd.

P.O. Box 2

Huntington, Cambridgeshire, PE18 6ES, England

Sponsor: Novartis Crop Protection, Inc.

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Laboratory Report ID: CBG 471/89310

MRID No.: 443874-06

4. **REVIEWED BY:** Stephen Carey, Biologist, ERBIII, EFED

Signature: *Stephen Carey*

Date: 11/19/98

5. **APPROVED BY:** Harry Craven, ERBIII, EFED

Signature: *Harry Craven*

Date: 11/19/98

6. **STUDY PARAMETERS**

Scientific Name of Test Organism: *Colinus virginianus*

Test Organisms Age/Size: >16 week of age

Definitive Study Duration: 14 days

7. **CONCLUSIONS:**

Results Synopsis

LD₅₀: >2000 mg ai/kg

NOEL: >2000 mg ai/kg

95% C.I.: N/A

Probit Slope: N/A



8. ADEQUACY OF THE STUDY**A. Classification:** Core**B. Rationale:** N/A**C. Repairability:** N/A**9. GUIDELINE DEVIATIONS**

1. N/A

2. N/A

10. SUBMISSION PURPOSE:**11. MATERIALS AND METHODS****A. Test Organisms**

| Guideline Criteria | Reported Information |
|--|--|
| Species: A wild waterfowl species, preferably the mallard (<i>Anas platyrhynchos</i>), or an upland game bird species, preferably the bobwhite (<i>Colinus virginianus</i>). | <i>Colinus virginianus</i> |
| Age at beginning of test: At least 16 weeks old. | >16 weeks old |
| Supplier | D.R. and R.E. Wise Monkfield, Bourn, Cambridgeshire, England |
| Acclimation period: At least 15 days. | 14 days |

B. Test System

| Guideline Criteria | Reported Information |
|--|----------------------|
| Pen facilities adequate? | Yes |
| Photoperiod: 10-h light, 14-h dark is recommended. | 7-h light, 17-h dark |
| Diet was nutritious and appropriate for species? | Yes |
| Feed withheld at least 15 hours prior to dosing? | Yes |

C. Test Design

| Guideline Criteria | Reported Information |
|---|--|
| Range finding test? | Yes |
| Definitive Test Nominal concentrations: At least five, in a geometric scale, unless $LD_{50} > 2000$ mg/kg ai | Three dose levels of 500, 1000, and 2000 were used. The resulting LD_{50} was greater than 2000 mg ai/kg |
| Controls: Water control or vehicle control (if vehicle is used) | Vehicle control |
| Number of birds per group: 10 (strongly recommended) | 10 birds (5 males and 5 females) |
| Vehicle: Distilled water, corn oil, propylene glycol, 1% carboxymethylcellulose, or gum arabic. | Corn oil |
| Amount of vehicle per body weight: Constant volume/weight % of body weight, not to exceed 1% (1ml/100g). | 10 ml/kg |
| Observations period: At least 14 days. | 14 days |

12. REPORTED RESULTS

| Guideline Criteria | Reported Information |
|--|--|
| Quality assurance and GLP compliance statements were included in the report? | Yes |
| Individual body weights measured at beginning of test, on day 14 and at end of test if extended beyond 14 days? | Yes |
| Mean feed consumption measured at beginning of test, on day 14, and at end of test if extended beyond 14 days? | Yes |
| Control Mortality: Not more than 10% | 0 % |
| Raw data included? | Yes |
| Signs of toxicity (if any) were described? | No, food consumption slightly higher in controls over days 8 - 14. |

Mortality

| Dosage (mg/kg) | No. of Birds | Cumulative Number of Dead | | | | | | | |
|-------------------|-----------------|---------------------------|---|---|---|---|-----|------|-------|
| | | Day of Study | | | | | | | |
| | | 1 | 2 | 3 | 4 | 5 | 6-8 | 9-11 | 12-14 |
| Control | 10 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 500 | 10 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 1000 | 10 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 2000 | 10 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |

Other Significant Results: All bodyweight changes were considered to be within normal limits, and food consumption was variable in all groups.

Reported Statistical Results

Statistical Method:

LD₅₀: >2000 mg ai/kg 95% C.I.: N/A

NOEL: 2000 mg ai/kg Probit Slope: N/A

13. Verification of Statistical Results

Statistical Method: visual estimation

LD₅₀: >2000 mg ai/kg 95% C.I.: N/A

NOEL: 2000 mg ai/kg Probit Slope: N/A

- 15. REVIEWER'S COMMENTS:** This study is scientifically sound and fulfills the guideline requirements for an acute oral LD50 test using bobwhite quail. Based on mean measured concentrations, the 14-day LD50 was determined to be greater than 2000 mg ai/kg, which classifies CGA-185072 as practically non-toxic to the bobwhite. The NOEC was determined to be 2000 mg ai/kg. This study is classified as **Core**.